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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/465,747 06/06/95 BROWN C DAKO-2/CONT

INTELLECTUAL PROPERTY GROUP
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HM12/0824

EXAMINER

MOSHER, M

ART UNIT

PAPER NUMBER

1648

36

DATE MAILED:

08/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.
08/465,747

Applicant(s)
Brown

Examiner
Mosher

Group Art Unit
1648



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☒ expires 4 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on 8/9/00 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- ☐ The proposed amendment(s):
- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
 - ☐ will not be entered because:
 - ☐ they raise new issues that would require further consideration and/or search. (See note below).
 - ☐ they raise the issue of new matter. (See note below).
 - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

- ☐ Applicant's response has overcome the following rejection(s): _____

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attachment.

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: 56

Claims rejected: 54, 55, and 57

- ☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

- ☒ Other See attached PTO-892.

Art Unit: 1648

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Mosher.

Claim Rejections - 35 USC § 112

Claim 54 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for virus-like particles comprising VP1 and VP2, does not reasonably provide enablement for virus-like particles comprising VP1 in the absence of VP2, for reasons of record in papers 27 and 30.

Applicant argues that the specification is enabling for making VP1 protein in the absence of VP2. The examiner agrees that the specification is enabling for production of VP1 protein in the absence of VP2. However, the claim is not drawn to VP1 protein, but to virus-like particles comprising VP1. Evidence of record indicates that VP1 does not assemble into virus-like particles in the absence of VP2. As cited in the previous office actions, Young et al (5,508,186) is cited as objective evidence that VP1 fails to form a virus-like particle in the absence of VP2. See column 11 line 50 to column 12 line 23. Since this application's specification does not teach how to make virus-like particles in the absence of VP2, it is maintained that the full scope of the claimed subject matter is not enabled. Applicant's arguments regarding splicing and fusion are not understood; the issue is not teachings enabling expression of VP1 or VP2 protein, but teachings enabling virus-like particles.

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Claim Rejections - 35 USC § 102

Claim 55 remains rejected under 35 U.S.C. 102(b) as being anticipated by Ozawa et al (Journal of Biological Chemistry 263:10922-10926, 1988), for reasons of record in papers 27 and 30. Applicant argues that Ozawa et al did not isolate and purify B19 VP1 protein, because Ozawa et al used immunoprecipitation of B19 proteins for purposes of detection and demonstration. However, Ozawa's intent is not germane, since the claim is drawn to a composition of matter. The VP1 product produced by in vitro translation was clearly not present in its natural milieu, and therefore it can be considered as isolated; since immunoprecipitation increases the relative purity of VP1 compared to the starting material, the immunoprecipitated protein can be considered as purified. Therefore, the translated, immunoprecipitated protein does fit squarely within the four corners of the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 54 and 57 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Young et al (5,508,186), for reasons of record in papers 27 and 30. Applicant argues that the baculovirus-produced capsids are different from CHO-cell-produced capsids, because the capsids are found in different locations within the producing cells. While this may be a distinction between the producing cells, this does not necessarily mean that the ultimate capsid products have different characteristics. The quoted passage from Kajigagy et al (?) discusses differences in the process, not differences in the product made. Although applicant did not provide a copy of Bansai et al, a copy has been obtained and

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considered. The publication provides evidence of differences between capsids made by "late-passage 3-11-5 cells" containing "only a trace level of VP1 protein" and capsids produced by coinfection of cells with different ratios of VP1- and VP2- expressing baculoviruses. However, the patent's disclosure includes teachings of how to transfect CHO cells *de novo*, and the patent's figure 4 provides clear evidence of more than a trace level of VP1 protein in the initial CHO-cell products. Therefore, although the processes used to make the capsids are different, it is maintained that the processes can be used to make products with the same (or similar) characteristics and utility, and that the claimed product-by-process is not patentably distinct from the prior art product made by a different process.

The rejection of claims 55 and 56 under 35 U.S.C. 103(a) as being unpatentable over the combination of Wood et al with any of Sisk et al, Cotmore et al, or Ozawa et al (T) is withdrawn. Although applicant's arguments are not convincing, on reconsideration it is concluded that Wood et al teaches production of VP2 protein, and the secondary references do not provide adequate motivation to choose VP1 protein instead of VP2 protein, for expression in a baculovirus expression vector.

The rejection of claims 54 and 57 under 35 U.S.C. 103(a) as being unpatentable over Kajigaya et al in view of French et al and any of Sisk et al, Cotmore et al, or Ozawa et al (T) is withdrawn. On reconsideration, production of empty B19 capsids by coexpression of VP1 and VP2 in baculovirus vectors is seen as obvious to try, not obvious to succeed.

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Conclusion

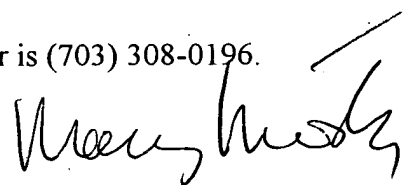
Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 22, 2000


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1200

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